BIOMET SPINE

MAR - 9 2010

510(k) Summary

Preparation Date:	November 20, 2009
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly, MS, RAC Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	Solitaire™ and Solitaire™ PEEK Anterior Spinal System with Solitaire™ Osteotite® Screws
Common Name:	Non-cervical spinal spacer
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic MAX & MQP

Device Description:

The Solitaire™ Osseotite® Screws are used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System. The screws are fabricated from Titanium alloy and are acid etched to create a roughened surface.

Indications for Use:

The Solitaire™ and Solitaire™ PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the Solitaire™ Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

Summary of Technologies:

The technological characteristics such as material, design and sizing of the Solitaire™ Osseotite® Screws in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are the same as, or similar to, the predicate devices.

Performance Testing:

Mechanical testing demonstrates that the Solitaire™ Osseotite® Screws when used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are substantially equivalent to other spacers currently on the market and is adequate for its intended use. Although animal data is not necessarily indicative of human clinical outcomes, animal testing has demonstrated that the roughened surface area of the screw increases osseointegration and enhances screw fixation strength in the spine in a healthy sheep model.

Substantial Equivalence:

The Solitaire™ Osseotite® Screws when used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicate intervertebral body fusion devices and vertebral replacement devices include the Solitaire™ and Solitaire™ PEEK (K022143, K062810, K081501 & K081395) from Biomet Spine as well as Biomet Trauma's Acid Etched Lag Screws (K070955) and the BioDrive® Cannulated Screw System (K082874) as predicates for the proprietary Osseotite® process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Biomet Spine
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K093629
Trade/Device Name: Solitaire™ and Solitaire™ PEEK Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: February 24, 2010
Received: February 25, 2010

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093629

Device Name: Solitaire™ and Solitaire™ PEEK Anterior Spinal System

Indications for Use:

The Solitaire™ and Solitaire™ PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093629